Section II (Remarks)

A. Summary of Amendments

By the present Response, claims 9, 12, 13, 17, 21, 22, 27, 31, 32, 39, and 44 have been amended, claims 1-8 have been cancelled, and claims 48-62 have been added, such that claims 9-62 are currently pending in the application. It is to be emphasized that claims 1-8 have been cancelled not for lack of patentability over the art, but rather to pursue new claims 55-64 which are directed to subject matter having greater commercial value to Applicant.

Claims 9, 27, and 44 have been amended to distinguish the "fluid chamber" from the "housing chamber;" to rename the "distal end" and "proximal end" as "inlet end" and "outlet end," respectively; to replace "passageway" with "passage;" to replace "there through" with "therethrough;" and to clarify that the gas pressure is greater than about 1 atm *when inside the housing chamber*.

Claims 12-13 and 31-32 have been amended to recite that the recited elevated gas pressures exist "when [the gas is] inside the housing chamber."

Claim 17 has been amended to replace "distal end" with "inlet end."

Claim 21 and 39 have been amended to replace "connector" with "connection," consistent with the threaded "connection" recited in claim 9.

Claim 22 has been amended to replace "distal end" with "outlet end."

New claims 48-62 claim further salient features of the invention.

No new matter within the meaning of 35 USC § 132(a) has been introduced by the foregoing amendments.

B. Application Status

In the February 24, 2006 Final Office Action, claims 1, 2, 5, and 6 were finally rejected under 35 U.S.C. 103(a) as being unpatentable over Walter (Re. 25,129) ("Walter") in view of Osborn et al. (U.S. 6,068,899)("Osborn"). Claims 3, 4, 7, and 8 were objected to as depending on rejected base claims (i.e., claims 1 and 5, respectively).

Applicant filed a first Response to the February 24, 2006 Office Action on April 24, 2006. A first Advisory Action was issued on June 1, 2006, but such Advisory Action erroneously indicated (at page 1) claims "4, 7, and 8" as both "allowed" and "objected to," while failing to address the status of claims 9-47.

Applicant filed a second, Supplemental Response to the February 24, 2006 Office action on June 26, 2006. Thereafter, but NOT responsive to Applicant's Supplemental Response (filed on June 26, 2006), the Examiner mailed a second Advisory Action issued on June 29, 2006 indicating the true status of all claims 1-47. Finally, in response to Applicant's Supplemental Response, the Examiner mailed a third Advisory Action on July 25, 2006 indicating that the amendments proposed in the Supplemental Response would NOT be entered, as amendments to claim 5 would purportedly require additional consideration and search.

In view of the 6-month statutory deadline of August 24, 2006 relative to the February 24, 2006 Final Office Action, a Request for Continued Examination (RCE) is submitted herewith. Payment for the RCE fee of **$790.00** under 37 CFR 1.17(e) is authorized in the enclosed Credit Card Payment Form PTO-2038.

As indicated in the July 25, 2006 Advisory Action:

claims 9-47 are allowed;

claims 3, 4, 7, and 8 are objected to as dependent on rejected base claims; and

claims 1, 2, 5, and 6 are rejected.

As indicated previously herein, claims 1-8 have been cancelled. Accordingly, the rejections of those claims in the prior Actions is hereby moot.

C. Patentable Distinctions of New Claims Over the Cited References

Claims 9-47 have previously been indicated as allowable. Minor amendments to claims 9, 12, 13, 17, 21, 22, 27, 31, 32, 39, and 44 do not affect the allowability of the claims in this regard.

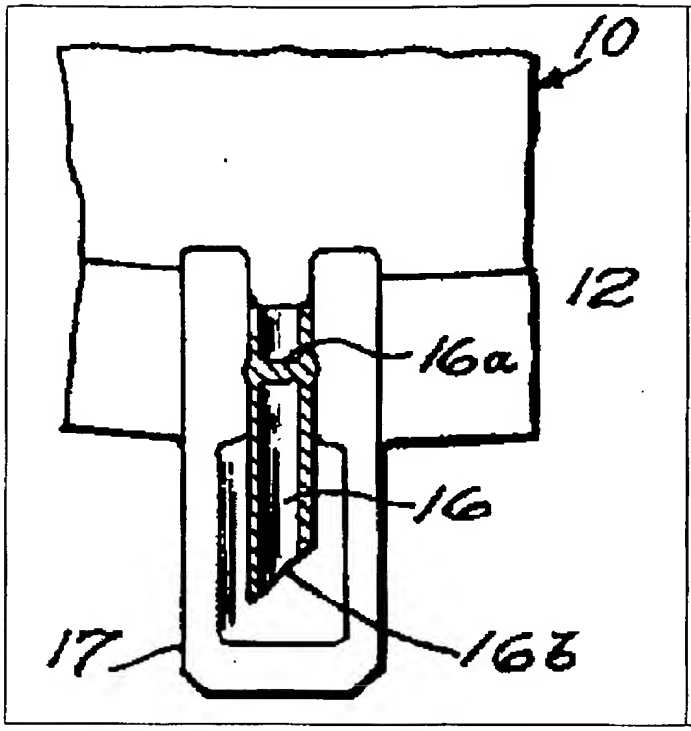
New claims 48-54 depend from (allowable) claims 9, 27, or 44, and are similarly allowable.

The remaining claims 55-64 include two independent claims, namely, claims 55 and 59. Such claims are similar in some aspects to prior independent claims 1 and 5, which had been rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Re. 25,129 to Walter ("Walter"). The rejection of prior claims 1 and 5 revealed the Examiner's fundamental misunderstanding of the disclosure of Walter, as detailed below.

1. Disclosure of Walter

Walter discloses an apparatus having multiple containers for holding a medical fluid such as blood, and then dispensing the fluid from the containers. For example, blood drawn by needle from a donor's arm flows by gravity through tubing into an ion exchange column and then into a bag 10 for storage. Walter, col. 6, lines 38-74. The bag 10 is fashioned from a thin flexible wall enabling the bag "to be completely **collapsed flatwise before filling, ridding it of air** and **precluding any appreciable liquid-gas interface.**" Id., col. 3, lines 27-30 (emphasis added). After filling, the bag 10 is sealed for storage. Id., col. 6, lines 56-75.

The bag 10 has an inlet tube 13 and a delivery tube 16 disposed at an outlet. Id., col. 3, lines 53-73. **Two separate seals are initially associated with the delivery tube** 16: a first inner seal comprising "a piercable diaphragm of about 1 mm thickness ... at the inner end of the tube, as indicated at 16a" (col. 4, lines 1-4) and "[a] protective tubular sheath 17 ... [enclosing] the protruding portion of the delivery tube ... ." Id., col. 4, lines 1-12. This sheath affords a second and outer seal for the delivery tube [16] so that the bag [10] is subject to a double seal at this location." Id., col. 4, lines 12-14. Such double sealing arrangement is illustrated below in Figure 3 of Walter, and accompanied by the names assigned to the various numbered elements appearing in the Figure. :



Deformable bag 10

End seal or closure strip 12

Delivery tube 16

Piercable diaphragm 16a

Open end 16b (of tube 16)

Tubular sheath 17

Manufacture of the above-illustrated bag outlet portion is described at columns 3-4 of Walter, as reproduced in pertinent part below:

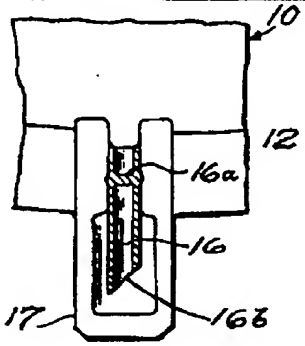
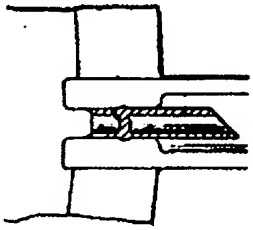
> The bag outlet is shown formed in the lower end-sealing strip 12 by a delivery to the 16 comprising a short length of the flexible tubing as for example 15 mm, or thereabouts inserted through an hermetically sealed into the seal strip 12 during the formation thereof, similarly as for the inlet tube 13. This delivery tube 16 is initially closed by a **pierceable diaphragm** of about one mm thickness formed of the like material, preferably at the inner end of the tube, as indicated at **16a**. The other and open end 16b is left protruding and may be beveled for guiding insertion of a piercing needle. A **protective tubular sheath 17** of the similar plastic is installed over and completely encloses the protruding portion of the delivery tube 16, with the inner end integrally joined with the end seal 12 of the bag, preferably simultaneously with the formation thereof, preventing bacterial contamination at the outlet. **This sheath 17 affords a second and outer seal for the delivery tube** so that the bag is subject to a **double seal** at this location.

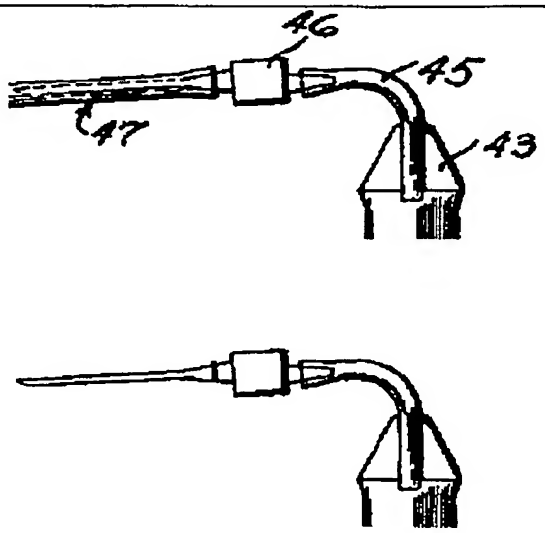
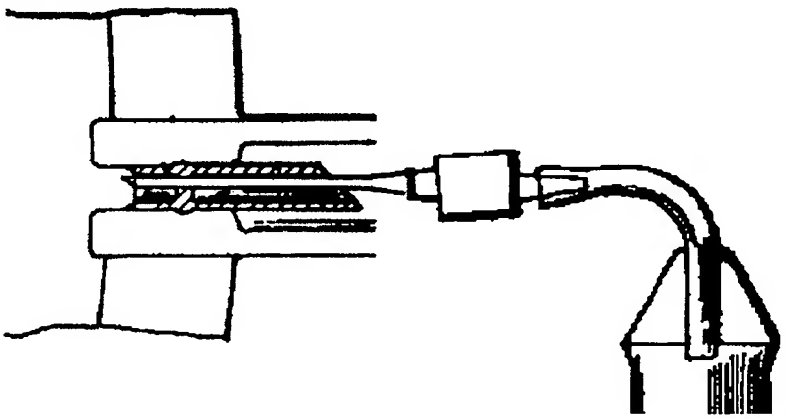
Walter, col. 3, line 71 – col. 4, line 14 (emphasis added).

Connecting operation of the bag of Walter is described at column 7 of Walter, as reproduced in pertinent part below:

> At the time of an infusion the **end of the protective sheath 17 is cut away from the delivery tube 16** at the bottom of the bag [10]. The **coupling needle 47** is then withdrawn from the sheathing tube 52 and is **inserted into and through the delivery tube 16** so as to **pierce the inner sealing diaphragm 16a** thereof and **provide a passage** for the blood."

Walter, col., 7, lines 5-10 (emphasis added). These critical operational steps are reproduced below.

Step	Illustration	Description
0		Initial state of bag (from Walter Figure 3)
1		"the **end** of the protective sheath 17 is **cut away** from the delivery tube 16"
2		**"coupling needle 47** is then withdrawn from the sheathing tube 52" (from Walter Figure 1)

Step	Illustration	Description
		
3		**"coupling needle 47 ... is inserted into and through the delivery tube 16** so as to **pierce the inner sealing diaphragm 16a** thereof and provide a passage for the blood"

Following piercing of the diaphragm 16a with the separate coupling needle 47, blood is delivered from the bag 10 through the hollow coupling needle 47, a tube 40, and an infusing needle to enter the recipient. Walter, col. 7, lines 5-32.

Walter repeatedly speaks to the necessity of avoiding contact between air and blood. See, e.g., Walter col. 1, lines 51 – col. 2, line 2; col. 3, lines 27-30; col. 7, line 68 – col. 8, line 2; col. 9, line 74 – col. 10, line 5; 7 claim 15. Obviously, to avoid possibility of embolism and stroke, it is essential to

ensure that the blood-containing bag 10 does not contain any air when the blood contained therein is administered to the recipient.

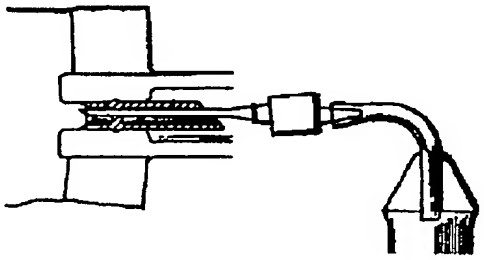
2. The Examiner's Mistaken Understanding of Walter

Against the backdrop of the foregoing summary of the disclosure of Walter, compare the following statements made by the Examiner mischaracterizing Walter:

> *"The connector that comprises a needle cannula 16 surrounded by a tubular sheath/diaphragm 17 in Walter is taught to be sealed to provide sterility for the cannula and its outlet from bacterial contamination. The sterility is maintained by being sealed, and* ***it is obvious that any air (i.e. a gas) will be within the sealed sheath*** *and remain there until the seal is broken and that the air/gas would be sterile.* ***Said cannula is used to pierce a tube at the time of use, thereby releasing the air.***

Such characterization indicates a faulty understanding of the disclosure of Walter in multiple respects.

First, **the cannula 16 of Walter (which is part of the claimed connector) is NOT used to pierce a tube** at the time of use; instead, a separate coupling needle 47 is used to provide piercing utility, as illustrated below..



Second, **the protective sheath 17 of Walter is NOT pierced by any "piercing element of a [] connector"** as required by claims 1, 2, 5, and 6. Instead, Walter expressly states that "the end of the protective sheath 17 is cut away from the delivery tube 16" before the coupling needle is inserted into and through the delivery tube 16 so as to pierce the inner sealing diaphragm 16a.

Third, **any "membrane" puncturing or piercing step of Walter does NOT generate any laminar flow of gas.** It is undisputed by the Examiner that the blood-containing bag of Walter is taught to be

devoid of air (see, e.g., Walter col. 3, lines 27-30, providing that the bag is "to be to be completely collapsed flatwise before filling, ridding it of air and precluding any appreciable liquid-gas interface"). The pierceable diaphragm 16a of Walter is in contact with the blood-containing interior of the bag 10. See, e.g., Walter col. 7, lines 7-11 ([t]he coupling needle is 47 is then ... inserted into and through the delivery tube 16 so as to pierce the inner sealing diaphragm 16a thereof and provide a passage for the blood"). To the extent that any gas is present behind the diaphragm 17 (and this assumption is disputed by Applicants in view of the lack of any disclosure of this feature by Walter), such gas is certainly released during step (1) in which "the end of the protective sheath 17 is cut away from the delivery tube 16," and piercing of the inner sealing diaphragm by the coupling needle 47 during step (3) provides contact with the blood chamber that is clearly devoid of any air or gas.

Fourth, **the Examiner's statement "it is obvious that any air (i.e. a gas) will be within the sealed sheath" is completely baseless and lacks any support in Walter**. Nothing in Walter teaches or fairly suggests that air should be present behind the sheath 17; the Examiner's statement is mere conjecture in this regard. The Examiner in this respect is respectfully reminded that she must explain with specificity what areas of the references suggest the combination. See, e.g., Ex parte Humphreys, 24 U.S.P.Q.2d 1255, 1262 (B.P.A.I. 1992); see also MPEP § 2143.03 (reference(s) must teach all of the limitations of the claims to support prima facie case of obviousness). The clear failure of the Examiner to identify support in Walter for the presence of any air behind the sheath – **let alone pressurized gas** – betrays the impropriety of any rejection of a claim reciting such limitation.

3. Patentable Distinctions of New Claims 55-64 over Walter

The remaining claims 55-64 include two independent claims, namely, claims 55 and 59.

New independent claims 55 and 59 recite:

> **55. A method comprising the steps of:**
> **connecting a source container adapted to hold a fluid to an inlet end of a hollow connector comprising a piercing element adjacent to an outlet end of the hollow connector, with the piercing element disposed in an essentially sterile gas at a pressure greater than about 1 atm, the gas being contained by a membrane;**
> **positioning the outlet end of the hollow connector adjacent to a target container;**

puncturing an opening in the membrane with the piercing element, wherein puncturing the opening generates a laminar flow of the gas along the sides of the opening; and

extending at least a portion of the hollow connector into the target container.

59. A method comprising the steps of :

enclosing a piercing element of a hollow connector within a membrane housing sealed from an external environment, the piercing element being adapted to puncture the membrane housing; and

inserting a gas that is essentially sterile into the membrane housing at a gas pressure sufficient to generate, when the piercing element punctures an opening in the membrane housing, a laminar flow of gas out of the membrane housing along sides of the opening.

(Emphasis added.)

Nothing in Osborn teaches or suggests all of the features of new claims 55 and 59.

As noted previously, nothing in Walter teaches or suggests that a gas should be present within the sealed sheath – *let alone* **pressurized gas** as required by claims 55 and 59 (see claim 55 "essentially sterile gas as a pressure greater than about 1 atm;" and claim 59 "gas pressure sufficient to generate [upon puncture] a laminar flow of gas out of the membrane housing").

Referring to claim 55, such claim further expressly requires the step of "piercing an opening in the membrane **with the piercing element [disposed in an essentially sterile gas contained by a membrane]**." As demonstrated previously, Walter fails to teach the piercing of any membrane by a piercing element contained by the membrane. Rather, Walter teaches that (1) the end of a protective sheath is cut away from a delivery tube; (2) a coupling needle is withdrawn from a sheathing tube; and (3) the bare coupling needle is inserted into and through the delivery tube to pierce an inner sealing diaphragm thereof. (See demonstrative figures and captions provided hereinabove.)

Likewise, referring to claim 59, such claim expressly requires a **piercing element [within a membrane housing]... adapted to puncture the membrane housing**. As discussed repeatedly herein, Walter fails to teach any piercing element within a membrane housing that is adapted to puncture the membrane housing. Instead, Walter teaches that (1) the end of a protective sheath is cut away from a delivery tube; (2) a coupling needle is withdrawn from a sheathing tube; and (3) the

bare coupling needle is inserted into and through the delivery tube to pierce an inner sealing diaphragm thereof. (See demonstrative figures and captions provided hereinabove.)

In view of the failure of Walter to teach or suggest the features of independent claims 55 and 59, such claims (along with claims 56-58 and 60-64 depending therefrom, respectively) are allowable over Walter.

D. Fees Due and Payable For Added Claims; and Calculation of Total Fees Payable Herewith

Claim fees corresponding to 5 independent claims and 49 total claims have been previously paid in the present application (see, e.g., Fee Transmittal dated September 16, 2003). By virtue of the present amendment, 5 independent claims and 56 total claims are now pending in the application. Thus, it is believed that excess claim fees corresponding to 7 total claims, calculated as (7 x $50.00) = $350.00 are due and payable as excess claims fees with the present Response.

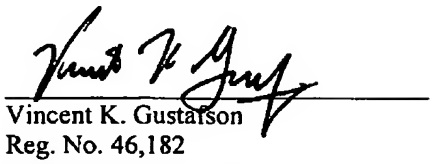
Accordingly, **total fee payment in the amount of $2,040.00** (including $900.00 for an additional two-month extension of time, $790.00 for the Request for Continued Examination, and $350.00 for excess claims) is authorized to be charged in the enclosed Credit Card Payment Form PTO-2038. If Applicant is mistaken in its calculation of fees currently due and payable, then any additional fee due and properly payable to enter the present Response is hereby authorized to be charged to deposit account number 08-3284 of Intellectual Property/Technology Law.

CONCLUSION

Favorable consideration of the enclosed amendments is respectfully requested. Claims 9-47 have previously been indicated as allowable; minor amendments thereto made herein do not change the patentable character of those claims. New claims 48-54 depend from allowable claims 9-47 and are similarly allowable. Claims 55-64 have been fully distinguished over Walter, which is believed to be the closest applicable prior art. A Notice of Allowance is earnestly solicited for all claims 9-64.

If any issues remain outstanding, incident to the formal allowance of the application, the examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss their resolution, in order that this application may be passed to issue without further delay.

Respectfully submitted,



Vincent K. Gustafson
Reg. No. 46,182
Attorney for Applicant

**INTELLECTUAL PROPERTY/
TECHNOLOGY LAW**
Phone: (919) 419-9350
Fax: (919) 419-9354
Attorney File No.: 2771-657(7497)

Enclosures:
Request for Continued Examination Form [1 pg]
Credit Card Payment Form PTO-2038 authorizing $2,040.00 [1 pg]

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